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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3761

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,878

Applicant(s)

ELLINGBOE ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 4, and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,540 to Abbot in view of US 5,462,416 to Dennehey. Abbot discloses a blood circuit with a cassette that serves to control fluid flow in a cardioplegia circuit. The disposable assembly or cassette 62 includes pumps, valves, and fluid lines therein (see FIG 2). The cardioplegia system diverts blood from a heart/lung machine (which pumps venous blood from a patient, oxygenates it, and returns it to the patient, see, generally item 14 in FIG 1), sends the oxygenated blood through cassette 62 and pump chamber/reservoir 74, where it is combined with cardioplegia solution and delivered to the patient. Furthermore, Abbot discloses a microprocessor controller and valves or flow control clamps 64, 88 that control the flow of fluid into the pump reservoir. Abbot fails to disclose tubing lines (though he does disclose fluid passageways), multiple valves, and sensors as positioned in the claimed cassette. Dennehey discloses a blood pumping cassette within a blood processing system with a plurality of tubing lines (134, 136) that connect to fluid passageways within the cassette. The cassette is comprised of a rigid portion connected to a flexible portion. (See FIG 9; column 6.) The blood circuit further comprises a control unit with a component interface region and an

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area that interfaces with the cartridge, and a pump. (See FIG 76; column 20.) The system further comprises blood reservoirs and other reservoirs that are used to dispense and receive liquids during processing (see column 5, line 65-67, column 6, lines 1-2, column 16, lines 40-45), flow control clamps located on all the various tubing lines, air bubble detectors (see column 10, lines 25-35). The cassette further comprises pressure sensors and valve stations that are actuated to regulate fluid flow (see columns 6-7). Abbot's clearly teaches that the use of the cassette system serves to simplify the fluid control, preventing the operator from having to manually set up the fluid channels in the complicated circuit. Dennehey also discloses that fluid pumping cassettes are desirable in the fluid handling art in order to centralize valving, pumping, and sensing operations (see column 1, lines 37-39, column 2, lines 44-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add the tubing lines, valves, and sensors, of the Dennehey device to the cassette disclosed by Abbott in order to provide a centralized, sealed fluid handling device to centralize valving, pumping, and sensing operations, as taught by Dennehey.

With regard to applicant's claim limitations drawn to the functions of the blood circuit, the pump, the reservoir, flow control clamp, sensors in the claims, the claims recite the functions of the devices in narrative form, and such recitations have not been given patentable weight. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language.

With regard to claim 4, Abbott disclose that the oxygenator is located fluidly upstream from the pump, rather than downstream, as claimed by applicant. However, applicant has not demonstrated any criticality in the order in which the blood is pumped or oxygenated. It would have been obvious to one having ordinary skill in the art at the time of invention to place an oxygenator downstream of the pumping cassette disclosed by Abbott, since it has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP 2144.04.

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,540 to Abbott in view of US 5,462,416 to Dennehey et al, further in view of US 5,820,579 to Plotkin. Abbot and Dennehey disclose the blood circuit and cassette as claimed including an air detector, but fail to disclose a valve with diverting mechanism. It is well known within the art of blood processing to provide air detectors and divert blood with bubbles in it so as not to introduce air bubbles into the patient, as taught by Plotkin. Plotkin discloses a cardiopulmonary bypass circuit with a pump and an oxygenator and an air detector 36. When the air detector senses a bubble in the line, microprocessor/controller 50 employs valve 38 to divert the blood and air bubble into recycle line 48, which serves as a reservoir, in order to prevent the air bubble from being introduced to the patient. Plotkin discloses that his system is better than conventional air trap systems, since the diverting technique diverts a minimum amount of fluid while maintaining adequate blood output to the patient (see column 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add a diverting mechanism to the cassette and air sensor of the

Abbot/Dennehey device in order to prevent introduction of air to the patient while maintaining adequate blood flow in the system.

Response to Arguments

4. Applicant's arguments filed 16 August 2005 have been fully considered. While the body of the previous final rejection addressed the combination of the Abbot and Dennehey references to render the instant claims unpatentable, the rejection was mistakenly set forth as one over Dennehey in view of Abbot. While the rationale behind the rejection remains the same, examiner has withdrawn the finality of the rejection mailed on 15 February 2005 in order to clarify the grounds of rejection. Accordingly, this action is made final.

5. Applicant argues that neither Dennehey nor Abbot disclose a disposable assembly with an oxygenator connected to a blood circuit. However, Abbott clearly discloses that his system incorporates a heart/lung machine that delivers oxygenated blood to the disposable cassette. Therefore, the prior art does, in fact, disclose an oxygenator in the blood circuit.

6. Applicant argues that the prior art does not disclose a reservoir to receive venous blood from a patient. Abbott discloses that his cassette diverts blood from a heart/lung machine, which takes venous blood from a patient, oxygenates it, and returns to the patient. Furthermore, Abbott discloses a pump reservoir that collects blood in the cassette and returns it to the patient. Therefore, the prior art shows a reservoir that receives venous blood from the patient. Furthermore, applicant's recitation of "venous

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blood" is a statement of the intended use of the claimed device. As long as the prior art device is capable of performing as claimed, it renders the instant invention unpatentable.

7. Applicant argues that the prior art does not disclose a flow control clamp.

However, Abbott clearly illustrates valves that control fluid flow to the pumping reservoir. See FIG 2).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd 
11 October 2005


PATRICIA BIANCO
PRIMARY EXAMINER
10/14/05